Form 21: 6 Week Follow-Up Assessment, Part I (Interview), Version 07/01/02 (A)

Section A: General Study Information for Office Use Only:

A1. STUDY ID#: LABEL

A2. VISIT # F/U 6 WEEKS.....FU6W

A3. DATE INTERVIEW COMPLETED: ___ ___ / ___ ___ / ___ ___ ___ ___
MONTH DAY YEAR

A4. INTERVIEWER'S INITIALS: ____ ____ ____

A5. INTERVIEW TYPE: IN-PERSON 1
TELEPHONE 2

A6. WHICH VERSION OF THIS FORM WAS USED? ENGLISH..... 1
SPANISH 2

SECTION B: PATIENT INTERVIEW

B1. Compared to before surgery, have you had an increase in your frequency of urination?

YES..... 1

NO..... 2

B2. Do you **currently** have to...

		YES	NO
a.	... strain to urinate?	1	2
b.	… bend forward to urinate?	1	2
c.	... lean back to urinate?	1	2
d.	... stand up to urinate?	1	2
e.	... press on your bladder to urinate?	1	2
f.	... push on the vagina or perineum to empty your bladder?	1	2
g.	... do anything else to urinate?	1 ↓	2

B2h. If yes, describe: _____

B3. How bothered are you by the way you now urinate compared to how you urinated prior to the surgery? Would you say...

Not at all bothered..... 1

Slightly bothered..... 2

Moderately bothered..... 3

Greatly bothered 4

B4. Would you describe your **current** urine stream as...

		YES	NO
a.	... a steady stream of urine?	1	2
b.	… a slow stream of urine?	1	2
c.	... a spurting, splitting or spraying stream of urine?	1	2
d.	... a hesitating stream of urine (stops and starts)?	1	2
e.	... dribbling after you have finished urinating?	1	2
f.	... some other description?	1↓	2

B4g. If yes, describe: _____

B5. How would you describe the **time it takes** to urinate now, compared to before your surgery? Would you say there's been no change, or does it seem to take more or less time to urinate now compared to before the surgery?

NO CHANGE 1

TAKES MORE TIME TO URINATE 2

TAKES LESS TIME TO URINATE 3

B6. Do you currently experience a feeling of incomplete bladder emptying?

YES 1

NO 2

B7. Next I have some questions about your <u>bowel movements.</u> Are you currently taking stool softeners?

YES 1

NO 2

B8. Do you have to strain to have a bowel movement?

YES 1

NO ..... 2➔ **SKIP TO B9**

B8a. How **often** do you have to strain to have a bowel movement? Would you say….

Less than or equal to 25% of the time? 1

More than 25% of the time? 2

B9. Do you have leaking or loss of control of gas?

YES..... 1

NO..... 2➔ **SKIP TO B10**

B9a. How **often** does this happen? Would you say….

less than once a month?..... 1

more than once a month but less than once a week?..... 2

more than once a week but less than every day?..... 3

every day?..... 4

B10. Do you have leaking or loss of control of liquid stool?

YES..... 1

NO..... 2➔ **SKIP TO B11**

B10a. How **often** does this happen? Would you say….

less than once a month?..... 1

more than once a month but less than once a week?..... 2

more than once a week but less than every day?..... 3

every day?..... 4

B11. Do you have leaking or loss of control of solid stool?

YES..... 1

NO..... 2➔ **SKIP TO B12**

B11a. How **often** does this happen? Would you say….

less than once a month?..... 1

more than once a month but less than once a week?..... 2

more than once a week but less than every day?..... 3

every day?..... 4

B12. Next, I have some questions about pain. Are you currently taking any medication(s) for pain? (PROBE: Are you still taking _____? [PAIN MEDICATION PRESCRIBED AT DISCHARGE (SEE VCS)]

YES..... 1

NO..... 2 ➔ **SKIP TO B15**

B13. What (which) pain medication(s) do you currently take?

	a.	b.	c.
	MEDICATION NAME AND FORM (PILL, TABLET, LIQUID, ETC.)	**STRENGTH PER RX'D DOSE**	**# OF DOSES TAKEN YESTERDAY**
1			_____ _____
2			_____ _____
3			_____ _____

B14. Do you take this /(any of these) medication(s) specifically for pain related to your (recent) surgery for urinary incontinence?

YES..... 1➔ **SKIP TO B16**

NO..... 2

B15. Do you have any physical pain that you feel is directly related to your (recent) surgery for urinary incontinence?

YES..... 1

NO..... 2 ➔ **SKIP TO B17**

B16. Using a 10-point rating scale, where 0 is ***'no pain'*** and 10 is the ***'worst possible pain***', tell me how you would rate that pain. Remember, we want to know about pain that you feel is directly related to your recent surgery for urinary incontinence. (CIRCLE ONE)

0	1	2	3	4	5	6	7	8	9	10
No Pain										**Worst Possible Pain**

B17. Have you returned to full normal activities of daily life (including work, if applicable) since the surgery?

YES..... 1

NO..... 2 ➔ **SKIP TO C1**

B18. (Approximately) how many days did it take you to return to full normal activities of daily life (including work, if applicable) after surgery?

____ ____ DAYS

B19. How many **paid** workdays did you take off after surgery?

____ ____ DAYS

(IF UNEMPLOYED OR RETIRED, CODE -1)

Affix ID Label Here

SECTION C: HEALTH SERVICES UTILIZATION

C1. DOES THE PATIENT REPORT OR IS THERE EVIDENCE OF ANY **PHYSICIAN VISITS** SINCE SURGERY? ASK,

Have you seen a doctor (nurse practitioner, physician's assistant) for any reason since your surgery?

YES..... 1

NO..... 2 ➔ **SKIP TO C3**

C2. DATES OF AND REASONS FOR ANY **PHYSICIAN VISITS;** ASK,

What was (were) the (approximate) date(s) and reason(s) for the physician (NP, PA) visit(s) since your surgery?

SOURCE CODES: 1 = PATIENT; 2 = MEDICAL RECORD; 3 = BOTH PT AND RECORD, 5 = PT REPORT AND SENT FOR MR. ⬇

	a.	b.	c.
	APPROXIMATE DATE	**REASON FOR THE VISIT**	**SOURCE CODE**
1	___ ___ / ___ ___ / ___ ___ ___ ___	_____	_____
2	___ ___ / ___ ___ / ___ ___ ___ ___	_____	_____
3	___ ___ / ___ ___ / ___ ___ ___ ___	_____	_____

C3. DOES THE PATIENT REPORT OR IS THERE EVIDENCE OF ANY **EMERGENCY ROOM VISITS** SINCE HER SURGERY? ASK,

Have you been to an emergency room for any reason since your surgery?

YES..... 1

NO..... 2 ➔ **SKIP TO C5**

C4. DATES OF AND REASONS FOR ANY **EMERGENCY ROOM** VISIT(S), ASK,

What was (were) the (approximate) date(s) and reason(s) for the emergency room visit(s) since your surgery?

SOURCE CODES: 1 = PATIENT; 2 = MEDICAL RECORD; 3 = BOTH PT AND RECORD, 5 = PT REPORT AND SENT FOR MR. ⬇

	a.	b.	c.
	APPROXIMATE DATE	**REASON FOR THE ER VISIT**	**SOURCE CODE**
1	___ ___ / ___ ___ / ___ ___ ___ ___	_____	_____
2	___ ___ / ___ ___ / ___ ___ ___ ___	_____	_____
3	___ ___ / ___ ___ / ___ ___ ___ ___	_____	_____

Affix ID Label Here

C5. DOES THE PATIENT REPORT OR IS THERE EVIDENCE OF ANY **NEW ABDOMINAL OR PELVIC SURGERY** SINCE HER UITN SURGERY? ASK,

Have you had any new abdominal or pelvic surgery since your UITN surgery?

YES..... 1

NO..... 2 ➔ **SKIP TO C7**

C6. DATES OF AND DESCRIPTION OF NEW ABDOMINAL OR PELVIC SURGERIES. ASK,

Tell me more about these surgeries.

SOURCE CODES: 1 = PATIENT; 2 = MEDICAL RECORD; 3 = BOTH PT AND RECORD, 5 = PT REPORT AND SENT FOR MR. ↓

	a.	b.	c.
	DATE OF SURGERY	**NAME OF SURGERY**	**SOURCE CODE**
1	___ ___ / ___ ___ / ___ ___ ___ ___	_____	_____
2	___ ___ / ___ ___ / ___ ___ ___ ___	_____	_____
3	___ ___ / ___ ___ / ___ ___ ___ ___	_____	_____

C7. OTHER THAN ANY DESCRIBED ABOVE IN C6, DOES THE PATIENT REPORT OR IS THERE EVIDENCE OF ANY **HOSPITAL ADMISSIONS** SINCE HER SURGERY? ASK,

Have you been hospitalized for any (other) reason since your surgery?

YES..... 1

NO..... 2 ➔ **SKIP TO C9**

C8. DATES OF AND REASONS FOR **HOSPITAL ADMISSIONS**. ASK,

What was (were) the (approximate) date(s) and reason for each hospitalization that occurred since your surgery?

SOURCE CODES: 1 = PATIENT; 2 = MEDICAL RECORD; 3 = BOTH PT AND RECORD, 5 = PT REPORT AND SENT FOR MR. ↓

	a.	b.	c.
	APPROXIMATE DATE	**REASON FOR HOSPITALIZATION**	**SOURCE CODE**
1	___ ___ / ___ ___ / ___ ___ ___ ___	_____	_____
2	___ ___ / ___ ___ / ___ ___ ___ ___	_____	_____
3	___ ___ / ___ ___ / ___ ___ ___ ___	_____	_____

Affix ID Label Here

C9. DOES THE PATIENT REPORT OR IS THERE EVIDENCE OF **ANY ANTIBIOTICS** PRESCRIBED SINCE DISCHARGE? ASK ABOUT ANTIBIOTICS PRESCRIBED AT DISCHARGE. (SEE THE PATIENT'S VCS.) DON'T RECORD THE SINGLE Rx PRESCRIBED AT DISCHARGE UNLESS IT WAS RENEWED OR REPRESCRIBED. ASK,

Since your surgery, has a doctor prescribed any antibiotics?

YES 1

NO ..... 2 ➔ **SKIP TO D1**

C10. RECORD EACH ANTIBIOTIC BY NAME

SOURCE CODES: 1 = PATIENT; 2 = MEDICAL RECORD; 3 = BOTH PT AND RECORD, 5 = PT REPORT AND SENT FOR MR. ↓

	a.	b.	c.	d.	e.
	ANTIBIOTIC NAME (PRINT NAME PRECISELY)	**NUMBER OF DAYS TAKEN**	**IS THE PATIENT STILL TAKING THIS MEDICATION?**	**REASON PRESCRIBED**	**SOURCE CODE†**
1		_____ _____	YES..... 1 NO 2		_____
2		_____ _____	YES..... 1 NO 2		_____
3		_____ _____	YES..... 1 NO 2		_____

SECTION D: SUMMARY OF ADVERSE EVENTS/COMPLICATIONS

D1. AS INDICATED BY THE RESPONSES RECORDED FOR THE PRECEDING QUESTIONS, IS THERE ANY EVIDENCE OF ANY **ADVERSE EVENTS OR COMPLICATIONS** RELATED TO THE PATIENT'S UITN SURGERY OR ANY STUDY PROCEDURES?

YES..... 1➔ **REMINDER: DOCUMENT ON FORM 22 AND COMPLETE ADVERSE EVENT FORM(S), IF REQUIRED**

NO..... 2